

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

R.M. BERRY, on Behalf of Himself and all
Others Similarly Situated,

Plaintiff,

v.

REPROS THERAPEUTICS, INC., JOSEPH
PODOLSKI, PAUL LAMMERS, and LOUIS
PLOTH, JR.,

Defendants.

Civil Action No.

JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

1. This is a securities class action on behalf of all persons who purchased common stock of Repros Therapeutics, Inc. (“Repros” or the “Company”) between July 1, 2009 and August 3, 2009 (the “Class Period”), against Repros and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 (“1934 Act”) and were injured thereby.

2. Defendant Repros is a pharmaceutical company that conducted a clinical trial for its drug Proellex, which was designed to treat symptoms associated with uterine fibroids and endometriosis. On July 1, 2009, Repros issued a press release stating that the drug showed substantial promise and had minimal side effects. However, in reality, Proellex elevated liver enzymes to dangerous levels. By August 3, 2009, the extent of these problems was fully revealed, and Repros announced the cancellation of the clinical trial. However, during that time, the price of Repros dropped over 73% from a close of \$4.96 on July 1, 2009 to a close of \$1.31 on August 3, 2009.

JURISDICTION AND VENUE

3. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. Section 78j(b) and Section 78t(a), and Rule 10b-5, 17 C.F.R. Section 240 10b-5, promulgated thereunder by the SEC.

4. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Repros's principal executive office is located in this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, the defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including the mails, telephone communications and the facilities of national securities exchanges.

PARTIES

6. Plaintiff R.M. Berry purchased common stock of Repros during the Class Period. A certification attesting to this purchase is attached hereto.

7. Defendant Repros Therapeutics, Inc., develops "oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders." One of its two products, Proellex, was created to treat symptoms associated with uterine fibroids and endometriosis. Repros's principal executive offices are located at 2408 Timberloch Place, Woodlands, Texas.

8. Defendant Joseph Podolski served as Repros's Chief Executive Officer and a director during the Class Period.

9. Defendant Paul Lammers served as Repros's President during the Class Period.

10. Defendant Louis Plotl, Jr. served as Repros's Chief Financial Officer and a director during the Class Period.

11. Defendants Podolski, Lammers, and Plotl are referred to collectively as the "Individual Defendants."

CLASS ACTION ALLEGATIONS

12. Plaintiff brings this action as a class action pursuant to Federal Rules of Civil Procedure 23(a) and 23(b)(3) on behalf of a Class, consisting of all persons who purchased or otherwise acquired Repros common stock between July 1, 2009 and August 3, 2009, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, members of the immediate family of any Individual Defendant, any subsidiary or affiliate of Repros and the directors, officers and employees of Repros or its subsidiaries or affiliates, or any entity in which any excluded person has a controlling interest, and the legal representatives, heirs, successors, and assigns of any excluded person.

13. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds if not thousands of members of the Class located throughout the United States. As of March 6, 2009, there were 15,174,904 million shares of Repros common stock outstanding. Throughout the Class Period, Repros common stock was actively traded on the NASDAQ (an open and efficient market) under the symbol "RPRX." Record owners and other members of the Class may be identified from records maintained by Repros and/or its transfer agents and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

14. Plaintiff's claims are typical of the claims of other members of the Class as all members of the Class were similarly affected by defendants' wrongful conduct in violation of the federal law that is complained of herein.

15. Plaintiff will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

16. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether the 1934 Act was violated by Defendants;
- b. whether Defendants omitted and/or misrepresented material facts;
- c. whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- d. whether Defendants knew or deliberately disregarded that their statements were false and misleading;
- e. whether the prices of Repros's publicly traded securities were artificially inflated; and
- f. the extent of damage sustained by Class members and the appropriate measure of damages.

17. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually

redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

SUBSTANTIVE ALLEGATIONS

18. Repros develops “oral small molecule drugs for major unmet medical needs that treat male and female reproductive disorders.” Repros has two products in development, Proellex and Androxal. Proellex was developed for to treat three medical problems: 1) anemia associated with uterine fibroids, 2) chronic treatment of symptoms associated with uterine fibroids, and 3) chronic treatment of symptoms associated with endometriosis.

19. In February 2009, Repros concluded a Phase II clinical trial for use of Proellex for the treatment of endometriosis. The trial tested two doses of Proellex, 25mg and 50mg, as a once-a-day oral therapy versus placebo in a double-blind design. Repros’s Form 10-K, filed with the Securities Exchange Commission (“SEC”) on or around March 16, 2009, stated that “[w]e are preparing to request an end of Phase 2 meeting with the FDA that we anticipate could occur mid-year 2009. Pending positive FDA outcome from that meeting and acceptance of clinical protocols, we plan to initiate registration Phase 3 pivotal trials as soon as practicable. We estimate the filing of a NDA for endometriosis in late 2010-2011.”

20. On July 1, 2009, the beginning of the Class Period, Repros announced the results of the Phase II trial, and issued a press release stating as follows:

The Phase II study that Repros completed earlier this year demonstrated clinically and statistically significant reductions of the three key pain symptoms commonly experienced by women with endometriosis: dysmenorrhea (painful menses), non-menstrual pelvic pain, and dyspareunia (painful intercourse). Additionally, the reduction of pain was accompanied by a statistically significant reduction in the number of patients requiring pain medication in both doses in this Phase II study compared with placebo. The study showed no efficacy differences between the 25 mg and 50 mg doses.

Furthermore, Repros has decided to discontinue the use of the higher, 50 mg dose in its ongoing studies in women with chronic symptomatic uterine fibroids and anemia associated with this condition due to an observed dose-dependent increase in liver enzymes in a low percentage of women. To date, Repros has dosed over 600 patients, and over 200 patients have completed at least one dosing period followed by an off-drug interval. From completed studies as well as from the ongoing large open label trial, it has been determined that the drug is well tolerated with few women discontinuing treatment due to adverse events.

Repros believes that the decision to discontinue the higher dose will most likely improve the benefit/risk profile of the drug. To date, there has been no evidence for an increase in efficacy at the 50 mg dose. In addition, earlier studies have demonstrated highly effective control of excessive menstrual bleeding and clinically significant improvement in quality of life parameters at the lower doses of 12.5 and 25 mg.

To further support the efficacy of the lower doses of Proellex, Repros will also initiate additional placebo-controlled studies with the 12.5 mg dose to supplement the overall efficacy and safety profile of the drug in these important indications. Repros does not expect that these additional studies will adversely affect the timing of its regulatory submissions and remains committed to its target date for filing NDAs for the uterine fibroids indications in the second half of 2010.

21. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 2, 2009, which was signed by Defendant Plotl.

22. The above press release contained the following material misrepresentations and/or omissions:

a. it falsely stated that Proellex was “well tolerated” with few women discontinuing treatment due to adverse events; and

b. it failed to reveal that the issues regarding liver enzymes could lead to the cancellation of the Proellex trials, which could lead to failure to meet the NDA target date and liquidity problems for Repros.

23. On July 7, 2009, Repros issued a press release stating as follows:

The Woodlands, Texas — July 7, 2009, Repros Therapeutics (NasdaqGM:RPRX) provides a further update on the clinical development of Proellex 25 and 12.5 mg doses.

Repros' recent decision to discontinue the use of the Proellex 50 mg dose in its ongoing clinical studies was based on observations of a dose-related increase in liver enzymes in a low percentage of women. The company believes that the 25 mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile.

Completed studies at 25 and 12.5 mg doses have demonstrated statistically and clinically significant control of excessive menstrual bleeding and improvement in quality of life parameters. In a completed Phase II study, which included 127 women with uterine fibroids, doses of 25 and 12.5 mg were compared to placebo for a period of three months. Both the 25 and 12.5 mg doses showed statistically significant ($p < 0.0001$) improvements in three clinically relevant endpoints: hemoglobin level, menstrual bleeding scores and quality of life parameters.

Repros believes that the decision to move forward with the 25 and 12.5 mg doses will improve the benefit/risk profile of Proellex. Additionally, Repros believes that any new studies required for the approval of the 12.5 mg dose will not adversely impact anticipated timing of NDAs for Proellex.

24. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 8, 2009, which was signed by Defendant Plotl.

25. The above press release contained the following material misrepresentations and/or omissions:

- a. it falsely stated that "the 25 mg and 12.5 mg doses will offer comparable efficacy benefits while providing an improved safety profile"; and
- b. it failed to reveal that the issues regarding liver enzymes could lead to the cancellation of the Proellex trials, which could lead to liquidity problems for Repros.

26. On July 23, 2009, the truth about Proellex was partially revealed when Repros issued a press release stating as follows:

Repros' recent decision to discontinue the use of the Proellex 50 mg dose in its ongoing clinical trials was based on observations of dose-related, clinically significant changes in liver enzymes ($\geq 3 \times$ Upper Limit of Normal, or ULN) in a low percentage of women. Following this decision, Repros notified all clinical sites involved in the studies of this important change, and all patients on the 50 mg dose have been switched to a 25 mg dose.

All subjects with liver enzyme elevations $\geq 3\times$ ULN had their treatment stopped and have been referred to an appropriate specialist for further evaluation. Of the nine subjects identified in the Press Release of July 7, 2009, with liver enzymes $\geq 3\times$ ULN on the 50 mg dose, the majority have had a reduction of their serum liver enzymes to within the normal range. Four of these subjects have not yet resolved and they are being followed closely. To date, no patient with elevated liver enzymes has required any type of additional treatment for this condition. All subjects in all ongoing trials are being monitored frequently to detect any type of change in liver enzyme levels.

As stated previously, Repros believes that the decision to move forward with the 25 mg and 12.5 mg doses will improve the benefit/risk profile of Proellex. The Company informed the Food and Drug Administration, or FDA, of the decision to discontinue the 50 mg dose on June 26, 2009, and intends to obtain guidance from the FDA in the coming months on the clinical and regulatory pathways forward for the Proellex clinical programs.

27. This press release listed Defendant Lammers as a contact person. It was submitted to the SEC via a Form 8-K, dated July 23, 2009, which was signed by Defendant Plotl.

28. The above press release contained the following material misrepresentations and/or omissions:

- a. it falsely stated that no patients that took Proellex would require “additional treatment” for elevated liver enzyme levels;

b. it failed to reveal that the issues regarding liver enzymes could lead to the cancellation of the Proellex trials, which could lead to liquidity problems for Repros.

29. On July 23, 2009, the stock closed at \$2.99, a 39% drop from a close \$4.92 the day before.

30. On August 3, 2009, Repros issues a press release announcing the suspension of Proellex clinical trials, based in a clinically significant increase in liver enzymes among participants:

The Woodlands, Texas —August 3, 2009, Repros Therapeutics (NasdaqGM:RPRX) announced today that, in the interest of patient safety, it is voluntarily suspending dosing of all patients in its clinical trials of Proellex. This decision is based on available information regarding the occurrence of clinically significant increases in liver enzymes with 50 mg and 25 mg doses of Proellex, coupled with recent input from a consulting panel of liver experts. The Company submitted a meeting request to the Food and Drug Administration (FDA) on July 30, 2009 and in response, FDA has proposed to change the topic of the previously scheduled End of Phase II meeting for endometriosis in late September into a discussion about the safety of Proellex and overall direction and scope of the program.

Suspension of Clinical Trials

The suspension of dosing will involve all ongoing clinical trials with Proellex for the treatment of chronic symptomatic uterine fibroids, anemia associated with this condition, and endometriosis. All of the patients in these trials were receiving a dose of 25 mg per day. Previously, Repros informed the clinical research organizations (CROs) running the clinical trials to switch all patients who had been receiving 50 mg per day in the ongoing clinical trials to the 25 mg dose. The 12.5 mg dose had been previously studied in earlier Phase II uterine fibroid and endometriosis trials, but no patients were receiving 12.5 mg per day in any trial at the time dosing was discontinued.

Elevation of Liver Enzymes

The data presented below has been acquired from unlocked, unaudited clinical trial databases which are being updated as new information becomes available from patients treated with Proellex or Placebo, and from recent lab tests.

As of July 27, 2009, the following estimates existed:

- More than 600 patients participated in double blind and open label clinical trials with exposure to Placebo, or various doses of Proellex for more than 1 month.
- Of these, approximately 500 received Proellex (approximately 190 had received a dose of 50 mg per day; approximately 260 received a dose of 25 mg per day; 55 received a dose of 12.5 mg per day) and approximately 130 received Placebo.
- Thirteen (13) subjects had an increase in liver enzymes greater than three times the upper limit of normal ($>3\times\text{ULN}$), all on Proellex, but in only 9 subjects was the increase in liver enzymes of $>3\times\text{ULN}$ confirmed by a repeat test in 48 hours as recommended in FDA's Guidance*. Each of these subjects either has been or is being followed closely with frequent monitoring of liver enzyme levels until the measurements return to baseline or normal or a decision is made by a consulting liver specialist that additional treatment is advisable.
- Of the 9 subjects with a confirmed increase in liver enzymes of $>3\times\text{ULN}$, 5 still had elevated enzymes as of July 27, 2009. These 5 patients had previously been dosed with the 50 mg

*FDA's 2009 Guidance for Industry, Drug Induced Liver Injury: Premarketing Clinical Evaluation dose. One of the 5 subjects was referred to a liver specialty clinic and was put on oral medication for treatment of her liver condition on July 26th. The Company was notified of this change in status on July 28th.

- Of the 9 subjects who had an increase in liver enzymes of $>3\times\text{ULN}$, 7 were severe enough elevations to be reported to the FDA as Serious Adverse Events (SAEs) (1 at a dose of 25 mg per day; 6 at a dose of 50 mg per day).

Financial Situation

Repros also announced that it is considering various financing alternatives to address its immediate short term liquidity needs. No assurance can be given that the Company will be successful in obtaining financing on acceptable terms or at all. The Company anticipates that if it is able to secure financing, that such financing will result in significant dilution of the ownership interests of its current stockholders and may provide certain rights to the new investors senior to the rights of its current stockholders, including but not limited to voting rights and rights to proceeds in the event of a sale or liquidation of the Company. In the event that the Company is unable to obtain adequate financing to meet its immediate short term liquidity needs, it will pursue other options, including but not limited to, reductions of expenses, sale of the

Company, sale or license of a portion or all of its assets, a bankruptcy filing or the liquidation of the Company.

31. This press release listed Defendants Podolski and Lammers as contact persons. It was submitted to the SEC via a Form 8-K, dated August 3, 2009, which was signed by Defendant Plotl.

32. On August 3, 2009, the stock closed at \$1.31, a 48% drop from a close \$2.53 the trading day before. This was a 73% drop from the close of \$4.96 on July 1, 2009.

33. On August 6, 2009, Repros issued a press release announcing that the FDA was placing Proellex on a clinical hold for safety reasons:

The Woodlands, Texas — August 6, 2009, Repros Therapeutics Inc. (NasdaqGM:RPRX) announced today that the Company received verbal notice on August 4, 2009 from the United States Food and Drug Administration (FDA) during a teleconference, requested by and held later that day with the Agency, that the Company's Investigational New Drug Applications (INDs) for Proellex have been placed on clinical hold for safety reasons. This action follows the Company's voluntary decision to suspend dosing of all patients in its clinical trials of Proellex (see press release dated August 3, 2009).

The Company and the FDA are scheduled to discuss the safety of Proellex and the overall direction and scope of the Company's clinical trials of Proellex at a meeting in late September. The FDA requested that the Company provide it with weekly updates about the patients who experienced a serious adverse event and still have elevated liver enzymes. The Company plans to provide such information as requested. In addition, at the September meeting Repros intends to present a detailed analysis of all of the patients with elevated liver enzymes, discuss the events that led to the suspension of the clinical trials, and determine whether and under which conditions, if any, the clinical hold may be lifted and the clinical trials of Proellex be safely resumed.

SCIENTER ALLEGATIONS

34. As alleged herein, defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated

to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. The misstatements involved core operations of Repros, as it involved the efficacy of one of its only two products. Furthermore, the Individual Defendants had access to information regarding the misstatements, as Proellex had approximately ten employees during that time. Furthermore, as set forth elsewhere herein in detail, Defendants, by virtue of their receipt of information reflecting the true facts regarding Repros, their control over, and/or receipt and/or modification of Repros's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Repros, participated in the fraudulent scheme alleged herein.

COUNT I

Pursuant to § 10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

35. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

36. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

37. Defendants violated § 10(b) of the 1934 Act and Rule 10b-5 in that they:

- a. employed devices, schemes and artifices to defraud;
- b. made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

c. engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Repros common stock during the Class Period.

38. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Repros common stock. Plaintiff and the Class would not have purchased Repros common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements. Moreover, at the end of the Class Period, when the inflation of the common stock was removed by the disclosure of the fraud, the Class suffered damages because they did not recover the inflation.

COUNT II

Pursuant to § 20(a) of the 1934 Act Against The Individual Defendants

39. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

40. Defendants Podolski, Lammers, and Plotz acted as controlling persons of Repros within the meaning of Section 20(a) of the 1934 Act as alleged herein. By virtue of their high-level positions, participation in and/or awareness of the Company's operations and/or intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of Repros, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's press releases alleged by Plaintiff to be misleading prior to and/or shortly after these

statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

41. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to have had the power to control or influence the particular statements giving rise to the securities violations as alleged herein, and exercised the same.

42. Furthermore, by engaging in the conduct alleged above, the Individual Defendants culpably participated in the fraud alleged above, directly and/or indirectly causing the investors' losses.

43. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the 1934 Act jointly and severally with Repros for Repros's violation of Section 10(b) and Rule 10b-5. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAAYER FOR RELIEF

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding Plaintiff and the other members of the Class damages, including interest;
- C. Awarding Plaintiff and the other members of the Class reasonable costs and attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: August 7, 2009

EMERSON POYNTER LLP

/s/ John G. Emerson
John Emerson, TX Bar No. 06602600
830 Apollo Lane
Houston, Texas 77058-2610
Telephone: (281) 488-8854
Facsimile: (281) 488-8867

Scott E. Poynter
Jack T. Patterson
Christopher D. Jennings
Gina M. Dougherty
EMERSON POYNTER LLP
500 President Clinton Ave., Ste. 305
Little Rock, AR 72201
Telephone: (501) 907-2555
Facsimile: (501) 907-2556

Brian P. Murray
Gregory B. Linkh
MURRAY, FRANK & SAILER LLP
275 Madison Avenue, 8th Floor
New York, New York 10016
Telephone: (212) 682-1818
Facsimile: (212) 682-1892

Counsel for Plaintiff